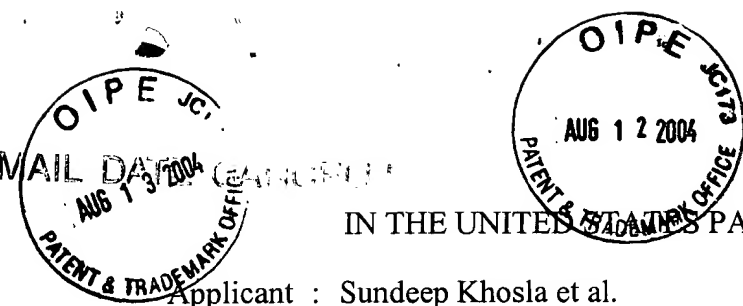


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Sundeep Khosla et al. Art Unit : 1654
 Serial No. : 09/972,809 Examiner : J. Russel
 Filed : October 5, 2001
 Title : TREATMENT OF OSTEOPOROSIS

MAIL STOP ISSUE FEE

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(B)

Applicants hereby petition for reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent application. Attached herewith is a copy of the Notice of Allowance including a Determination of Patent Term Adjustment under 35 U.S.C. 154(b), mailed May 13, 2004, for the above-referenced application. The Notice of Allowance states that the Patent Term Adjustment at allowance is 72 days. Reconsideration of the Patent Term Adjustment calculation to decrease Applicant Delay from 46 days to 36 days, and to increase Total PTA from 72 to 82 days, is respectfully requested.

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

A review of the Patent Term Adjustment History in the PAIR system shows that the United States Patent and Trademark Office (PTO) calculated the Patent Term Adjustment (PTA) as follows:

- A. The PTO mailed a Notice to File Missing Parts on January 16, 2002. The PAIR system indicates the "Application is Now Complete" on April 26, 2002, thereby according an Applicant Delay of 10 days. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct Applicant Delay is 0 days, as outlined further below.

08/13/2004 AADDF02 00000004 09972809

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200.00 DP

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV509497878US

August 12, 2004
 Date of Deposit

- B. The PTO mailed a delayed 14-month first non-final Office Action on April 2, 2003, thereby according a PTO Delay of 118 days. Applicants concur with this patent term adjustment calculation.
- C. Applicants submitted a response to the above-referenced non-final Office Action on August 4, 2003. The PAIR system indicates the PTO received the response on August 7, 2003, thereby according an Applicant Delay of 36 days. Applicants concur with this patent term adjustment calculation.

STATEMENT OF THE FACTS

On January 16, 2002, the PTO mailed a Notice to File Missing Parts (copy enclosed) requesting a signed inventors' oath or declaration and the missing parts surcharge fee. Applicants submitted a complete and timely Response to the Notice to File Missing Parts on March 15, 2002. The PAIR system and the PTO date-stamped postcard (copy enclosed) indicate that the PTO received Applicants' response on March 22, 2002. As Applicants' complete response was received within the three-month period of response ending April 16, 2002, Applicants should not be assessed any delay for the response to this Notice.

The application was not marked as "complete" in the PAIR system until April 26, 2002. As Applicant Delay is calculated until the application is "complete," Applicants were unduly accorded with a delay of 10 days. Thus, Applicants respectfully request correction of the "Application is Now Complete" entry in the PAIR system to be dated not later than March 22, 2002.

DOCUMENTS ENCLOSED

A copy of each of the following documents is provided herein:

- 1) Notice of Allowance mailed May 13, 2004;
- 2) Notice to File Missing Parts mailed January 16, 2002;
- 3) Response to Notice to File Missing Parts dated March 15, 2002, and PTO date-stamped postcard indicating receipt date of March 22, 2002.

REMARKS

In consideration of the events described above, Applicants believe the PTA calculation of 72 days is incorrect. Applicants respectfully request reconsideration of the patent term adjustment in the following manner:


- 1) Total PTO Delay should be calculated as 118 days (for a delayed first Office Action); and,
- 2) Total Applicant Delay should be calculated as 36 days (for delayed response to non-final Office Action).

Therefore, Applicants respectfully request the removal of 10 days of Applicant Delay, thus decreasing Applicant Delay from 46 days to 36 days and increasing the Total PTA from 72 to 82 days. Applicants also kindly request correction of the file history in the PAIR system to indicate the application was "complete" not later than March 22, 2003.

Enclosed is a check for the fee of \$200 required under 37 CFR §1.18(e). Please apply any other required charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: August 12, 2004



J. Patrick Finn III, Ph.D.
Reg. No. 44,109

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Notice of Allowability



CANCELLED

Application No.

09/972,809

Examiner

Jeffrey E. Russel

Applicant(s)

KHOSLA ET AL.

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE and IDS filed February 12, 2004.

2. ☒ The allowed claim(s) is/are 21 and 25-32.

3. ☒ The drawings filed on 12 September 2002 are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 20040212

4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.

7. ☐ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____.



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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on February 12, 2004 has been entered.

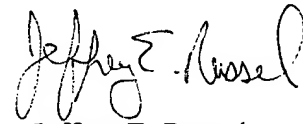
2. The following is an examiner's statement of reasons for allowance: The claimed invention is deemed allowable over the prior art of record or any combination thereof for the reasons set forth in the Office action mailed April 2, 2003, section 14. With respect to the references cited in the Information Disclosure Statement filed February 12, 2004, none of the references teaches or suggests the IGFBP2 required by the instant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 11, 2004